

Notice of Allowability

Application No.

09/901,535

Examiner

Monica A Fontaine

Applicant(s)

OLSON, LORIN

Art Unit

1732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 20 November 2003.
2. ☒ The allowed claim(s) is/are 30,31,33,40-46 and 48-55.
3. ☒ The drawings filed on 09 July 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date <u>021904</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

Art Unit: 1732

DETAILED ACTION

This office action is in response to the Amendment filed 20 November 2003.

All previous rejections have been overcome by said Amendment and the Examiner's Amendment contained herein.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Carol LaSalle on 19 February 2004.

The application has been amended as follows:

Claim 46, line 6, "and" has been deleted.

Claim 46, line 8, "." has been deleted.

Claim 46, line 8, "--; and--" has been added after the phrase "intersects said vertex".

Claim 46, the following five (5) lines have been added to the end of the claim:

--wherein said vertex defines a vertex angle,

a line extending from a center of said base to said vertex defines a structural axis, and

said open lumen defines a luminal axis, wherein said luminal axis and said structural axis intersect at an intersection angle.--

Art Unit: 1732

Claim 47 has been cancelled.

Claim 48, line 9, "and" has been deleted.

Claim 48, the following five (5) lines have been inserted between present lines 9 and 10:

--wherein said vertex defines a vertex angle,

a line extending from a center of said base to said vertex defines a structural axis, and

said open lumen defines a lumenal axis, wherein said lumenal axis and said structural axis intersect at an intersection angle, and--

Claim 54, lines 2-5 have been deleted.

Claim 55, lines 2-5 have been deleted.

Allowable Subject Matter

Claims 30, 31, 33, 40-46, and 48-55 are allowed.

The following is an examiner's statement of reasons for allowance: The prior art of record neither teaches nor suggests the claimed method of manufacturing a micro-needle structure for penetrating the skin and other tissue barriers wherein the micro-needle structure's lumenal axis and structural axis intersect at an intersection angle, and wherein the structural axis is defined by extending a line from the center of the conical structure's base to the cone's vertex, and the lumenal axis is defined by an open lumen within the micro-needle structure. Specifically, US 5,733,266 and/or WO 00/74763 do

Art Unit: 1732

not anticipate or suggest the present invention because neither of these documents mention intersecting luminal and structural axes as defined by applicant. Also, US 6,558,361 does not anticipated or suggest the present invention because its needle's structural axis (see element 32 in Figure 4), which extends from the center, or midpoint, of the conical structure to its cone's vertex, does not intersect with its luminal axis (see element 30, Figure 4).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monica A Fontaine whose telephone number is 571-272-1198. The examiner can normally be reached on Monday-Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Colaianni can be reached on 571-272-1196. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1732

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Maf
February 20, 2004



MICHAEL COLAIANNI
PRIMARY EXAMINER